NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC.,	:	
	:	
Plaintiff,	:	Civil Action No. 2:10-CV-06108(ES-CLW)
	:	
v.	:	
	:	**OPINION**
ROXANE LABORATORIES, INC.,	:	
	:	
Defendant.	:	**JULY 30, 2012**
	:	

CATHY L. WALDOR, United States Magistrate Judge.

I. Introduction

Pending before this Court is a motion by Defendant Roxane Laboratories, Inc., ("Roxane") for leave to amend its Local Patent Rule 3.7 Initial Invalidity and Non-Infringement Contentions. (Docket Entry No. 101, the "Motion"). Plaintiff Jazz Pharmaceuticals, Inc., ("Jazz") has opposed the Motion, in part, by way of two letters. (Docket Entry Nos. 107 ("Pl. Opp.") and 109 ("Supp. Opp.")). On March 19, 2012, Roxane filed a reply letter, in regard to its request to amend its Initial Invalidity Contentions. (Docket Entry No. 110, "Def. Reply" or "Defendant's Reply"). At the request of the Court, Roxane filed a supplemental letter on March 29, 2012. (Docket Entry No. 112, "Def. Supp. Letter" or "Defendant's Supplemental Letter"). On April 16, 2012, Jazz filed a surreply to Defendant's Reply. (Docket Entry No. 118, "Pl. Surreply"). On April 18, 2012, the Court held oral argument on the record. (Docket Entry No. 121, "Transcript"). The Court has reviewed the submissions in favor of and in opposition to the Motion and considered the arguments raised by the parties during oral argument. For the reasons set forth below, the Motion is hereby **DENIED**.

II. Background

Roxane filed an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market and distribute a generic sodium oxybate product stated to be the bioequivalent to Jazz's XYREM product. (Motion at 1-2). In response to Roxane's ANDA application, Jazz initiated three actions now consolidated into the above captioned matter. (Id.); (Docket Entry No. 1, Complaint, ("Compl.")) (Consolidated with Civil Action Nos. 11-660 and 11-2523). These consolidated matters are brought pursuant to the Hatch-Waxman amendments to the Federal Food, Drug and Cosmetics Act and to Title 35 of the United States Code (the "Hatch-Waxman Act"). (Motion at 1). At issue in this Hatch-Waxman Act litigation are eight patents, separated into two groups: (1) four related to the sodium oxybate product: U.S. Patent Nos. 6,472,431 (the "431 patent"), 6,780,889 (the "889 patent"), 7,262,219 (the "219 patent"), and 7,851,506 (the "506 patent") (collectively, the "Product Patents"); and (2) four related to the method of distributing the sodium oxybate product: U.S. Patent Nos. 7,668,730 (the "730 patent"), 7,765,106 (the "106 patent"), 7,765, 107 (the "107 patent"), and 7,895,059 (the "059 patent") (collectively, the "Distribution Patents"). (Id. at 2). The Product Patents are not at issue in this Motion. (Motion at 2).

The instant action was filed on November 22, 2010. (Compl. at 13). On February 7, 2011, the Honorable Madeline Cox Arleo, U.S.M.J., held an initial scheduling conference. (Docket Entry No. 12, Letter Order); (Minute Entry from February 7, 2011). During that conference, Judge Arleo reserved on setting a pretrial scheduling order to permit Jazz to obtain information from a third party in order to submit its Infringement Contentions. (Motion at 2). On March 22, 2011, Judge Arleo ordered that Roxane serve its Initial Invalidity and Non-Infringement Contentions by April 14, 2011. (Id.). On April 14, 2011, Roxane timely served its

Initial Invalidity and Non-Infringement Contentions. (Id.). Roxane's Invalidity Contentions cited twenty-two (22) prior art references. (Pl. Opp. at 2). Due to disputes between the parties, a formal scheduling order was not entered until September 1, 2011. (Motion at 2); (Docket Entry No. 60, Pretrial Scheduling Order ("PSO")). Opening Markman briefs were filed on December 5, 2011, expert discovery regarding Markman issues closed on January 5, 2012, and Markman briefing closed on February 3, 2012 with the filing of responsive Markman papers. (PSO at ¶¶ 7, 9, and 10).

During oral argument, Roxane stated that it was not until September of 2011, that it first recognized the prior art that is the subject of this Motion. (Transcript at 9:20-10:7). On January 30, 2012 and February 3, 2012, Roxane requested a meet and confer with Jazz, in order to discuss amending its Contentions. (Motion at 3). Roxane alleges that Jazz refused to meet and confer, accordingly, Roxane filed the instant Motion on February 27, 2012, seeking leave of Court to amend its Initial Invalidity Contentions to identify additional prior art as noted in Defendant's Supplemental Letter. (Id.). Specifically, Roxane seeks to amend its Initial Invalidity Contentions to add prior art references of: (a)(1) the FDA's Preliminary Clinical Safety Review of New Drug Application ("NDA") No. 21196 (the "FDA Safety Review"); (a)(2) Video of the Xyrem Prescription and Distribution Process submitted to the FDA on May 30, 2011 (the "Video"); (a)(3) Transcript of the Video noted in subsection (a)(2) (the "FDA Transcript"); (a)(4) a Briefing Booklet for the June 6, 2001 Meeting (the "Briefing Booklet"); (b)(1) a Presentation given to the National Association of Drug Diversion Investigators (the "NADDI Presentation"); (b)(2) a transcript of a June 6, 2001 proceeding for the Peripheral and Central Nervous System Drugs Advisory Committee meeting (the "PCNSDAC Transcript"); (c)(1) a print out of a screen shot of the FDA website listing the 2001 FDA Advisory Committee

Meeting Documents by Center; (c)(2) a print out of a screen shot of the web.archive.org of "CDER 2001 Meeting Documents"; and (c)(3) a print out of a screen shot of the web.archive.org of "Briefing Information" for June 2006 Meeting (Collectively "Screen Shots"). (Collectively "Alleged Prior Art" or "Documents").

III. Discussion

A. Legal Standard

Local Patent Rule 3.7 ("Rule 3.7") of the Local Rules of Civil Procedure, of the United States District Court, for the District of New Jersey, governs "[a]mendments of any contentions, disclosures, or other documents required to be filed or exchanged…." Where a party seeks leave to amend its invalidity contentions, it must do so "by order of the Court upon a timely application and showing of good cause." Id. The application shall disclose whether the adverse party consents or objects. Furthermore, Rule 3.7 only permits amendment "absent undue prejudice to an adverse party." Id. Thus, pursuant to Rule 3.7, a court may permit a party to amend its invalidity contentions provided the following three elements are established: (1) the moving party makes a timely application to the court; (2) there is good cause for the amendment; and (3) there is no undue prejudice to the adverse party.

In the context of patent litigation, Federal Circuit precedent governs the interpretation of local patent rules because such issues are "intimately involved in the substance of enforcement of the patent right." O2 Micro International Ltd. v. Monolithic Power Systems, Inc., 467 F.3d 1355, 1364 (Fed. Cir. 2006). The Local Patent rules "exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their case." Computer Accelerations Corp. v. Microsoft Corp., 503 F.Supp.2d 819, 822 (E.D. Tex. 2007). Specifically, the patent rules governing contentions are designed to encourage

parties to provide "early notice of their infringement and invalidity contentions and to proceed with diligence in amending those contentions when new information comes to light in the course of discovery." O2 Mircro, 467 F.3d at 1365-66. The local rules "seek to balance the right to develop new information in discovery with the need for certainty as to the legal theories." Id. While some leniency is extended in amending contentions, the local rules require "parties to crystallize their theories of the case early in the litigation." Id. at 1364.

Amendments to infringement and invalidity contentions are not granted as liberally as requests for amendments to pleadings, in part, because "the philosophy behind amending claim charts is decidedly conservative and designed to prevent the 'shifting sands' approach," to a party's contentions. King Pharmaceuticals. Inc. v. Sandoz, Inc., Civil No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010); Cf. FED. R. CIV. P. 15(a)(2). Particularly, in the District of New Jersey, the Local Patent Rules emphasize "*ultra* early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act." Sanofi-Aventis v. Barr Labs., Inc., 598 F. Supp. 2d 632, 637 (D.N.J. 2009) (emphasis in original).

B. Parties' Arguments

a. Roxane's Arguments in Support of the Motion

Roxane argues that it should be permitted to amend its Initial Invalidity Contentions because (1) Roxane recently discovered new, material prior art despite an earlier diligent search and (2) Jazz will not be unfairly prejudiced by Roxane's amendment. (Motion at 3-4). Specifically, Roxane is seeking to add new bases for invalidity of the Distribution Patents. (Id. at 2). Roxane states that it spent the ten (10) months following the submission of its Initial Invalidity Contentions further investigating its Contentions and attempting to confer with counsel for Jazz. (Id.). Part of that investigation included an independent search for publicly

available documents. (Transcript at 9:20-12:3). In doing that search, during September of 2011, Roxane discovered the Alleged Prior Art at issue in this Motion. (Id.). After discovery, Roxane states that it continued in its due diligence by evaluating the Documents and other materials in making a final determination that the Documents are prior art to the Distribution Patents. (Motion at 3). Roxane argues that the evaluation was no small undertaking because the Distribution Patents have claims totaling fifteen (15) columns or 7500 words. (Transcript at 13:10-14:7). Due to the Distribution Patents' complexity, it was not until February 27, 2012 that Roxane sought leave to amend its Invalidity Contentions. (Motion at 2). Furthermore, Roxane states that its request to amend its Invalidity Contentions was further delayed because it needed to ensure the Documents relied upon were publicly available and thus qualify as prior art. (Id.).

Roxane further argues that the Alleged Prior Art was not fully cited in the Distribution Patents' prosecution history. (Def. Reply at 3-4). Additionally, Roxane contends that Jazz failed to make a full disclosure of the Alleged Prior Art submitted to the FDA in the prosecution of the Distribution Patents. (Id.). Roxane also notes that the Video originally produced by Jazz was in an unreadable format, thus Roxane had to obtain it from a third party – causing further delay. (Transcript at 32:4-7).

Lastly Roxane argues that permitting it to amend its Invalidity Contentions poses no possible unfair prejudice to Jazz. (Motion at 4, Def. Reply at 7-8). To that end, Roxane states: (1) the Alleged Prior Art at issue is well known to Jazz; and (2) Roxane's Motion comes while fact discovery is still open. (Motion at 4).

b. Jazz's Arguments in Opposition to the Motion

Jazz argues that Roxane's Motion is untimely and fails to satisfy the "Good Cause" requirements. (Pl. Opp. at 2). As to its "Good Cause" arguments, Jazz states that Roxane's

discovery was not recent, that Roxane cannot prove that it conducted a diligent search, that the Alleged Prior Art sought to be added are not "Material" nor "Prior Art", and that Jazz will be unduly prejudiced if the Court permits this amendment. (Id.).

First, Jazz contends Roxane's Motion is untimely because the Alleged Prior Art on which Roxane intends to rely was produced by Jazz in July of 2011. (Id. at 3). However, it was not until February 27, 2012 that Roxane brought this Motion. Jazz takes the position that Roxane's delay in filing the Motion, once it had the Alleged Prior Art in its possession, has been grounds for denial of similar motions. (Id. 4-5).

Secondly, Jazz states that Roxane cannot prove the requisite elements to make a sufficient "Good Cause" showing. (Id. at 5). The discovery of Alleged Prior Art was not recent within the meaning of Rule 3.7. The Documents contained in or referred to in the prosecution history were known to Roxane in October of 2010, evidenced by Roxane's extensive reference to that file history. (Id.). Further, of the Alleged Prior Art Roxane's Motion seeks to add, said prior art was either in the prosecution history or duplicative of same. (Id.).

Next, Jazz argues that Roxane cannot show it was diligent in its search to develop its Invalidity Contentions because the Documents Roxane now intends to rely on were either part of the prosecution history and/or referred to on the face of the patent-in-suit. (Id. at 6, Transcript at 19:12-21:3). If Roxane was diligent in its earlier search, it would have found the Documents and included them in its invalidity contentions at the appropriate time. In fact, Jazz notes that throughout this litigation, Roxane heavily relied on the prosecution history and should have been aware of the existence of the Documents. (Pl. Opp. at 6). Furthermore, the Alleged Prior Art was publicly available before the initiation of this action. (Id.). Thus, it was either through

ignorance or apathy that Roxane failed to appropriately develop its Invalidity Contentions. (Transcript at 21:4-14). As such, Roxane cannot show that it was diligent.

Additionally, Jazz argues that the Alleged Prior Art Roxane seeks to add does not constitute "Prior Art" and is not "Material" for the purposes of Rule 3.7. (Pl. Opp. at 6-7). Where documents are not printed publication, that is, sufficiently accessible to the public interested in that art, those documents cannot constitute prior art. (Id. at 7). By way of example, Roxane seeks to add a presentation made to the FDA but does not show that the information was disseminated or made available to the relevant public. (Id.). As such, Roxane also fails to carry its "Good Cause" burden because it cannot show the documents are "Material Prior Art." (Id.).

Finally, Jazz argues that it will be unduly prejudiced if the amendment is permitted.[1] Specifically, Jazz states that it would be prejudiced because it has prepared its case for the last year around the Invalidity Contentions filed with the Court in April of 2011. (Id. at 9). In support of its argument, Jazz notes that claims construction briefing was completed prior to Roxane's Motion. (Id.). Further, that the amendment would delay this proceeding because it would undoubtedly result in the need for new discovery. (Id.). Thus, permitting Roxane to now amend its Invalidity Contentions would strategically and economically harm Jazz. (Id.).

C. Analysis

a. Timeliness

The Court finds that Roxane's application is not timely. The Federal Circuit has emphasized the importance of the "timely application" element by recognizing that "if the parties were not required to amend their contentions promptly after discovering new information, the

[1] As a threshold issue, Jazz states that if the Court finds that Roxane was not diligent and has not shown "Good Cause," then it is unnecessary to consider prejudice to Jazz. (Id. at 8).

contentions requirement would be virtually meaningless as a mechanism for shaping the conduct of discovery in trial preparation." O2 Micro, 467 F.3d at 1366.

Here, Roxane states that it discovered the Alleged Prior Art in September of 2011. (Transcript at 10:22-11:6). After the Documents were discovered, Roxane continued its due diligence by evaluating the Documents in order to determine whether they were material prior art. (Id. at 12:21-15:4). Roxane filed this Motion on February 27, 2012, approximately five (5) months after discovery. Roxane argues it did not file this Motion earlier because it was required to comply with FED. R. CIV. P. 11 in reviewing the Documents before bringing its Motion. (Def. Reply at 2).

This Court finds Roxane's argument unpersuasive. Roxane knew its Invalidity Contentions were filed in April of 2011. If Roxane came across newly discovered prior art in September of 2011, it should have reviewed the documents expeditiously and immediately raised the issue with the Court. Specifically, Roxane's argument that a five month review period constitutes diligence is not persuasive. As mentioned earlier, Roxane had previously conducted a lengthy Invalidity Contentions submission in April of 2011. Roxane should have been able to easily identify the newly discovered Alleged Prior Art and filed a motion to amend for the Court's review. In particular, Roxane admits that it did not bring the request to amend to Jazz's attention until January 30, 2012. (Def. Reply at 2). However, Jazz was operating under the previously filed contentions while Roxane reviewed and considered whether amending its invalidity contentions was appropriate. This is the exact concern the Federal Circuit Court addressed in emphasizing the importance of a timely application to amend contentions. See O2 Micro, 467 F.3d at 1366. Permitting Roxane to amend its invalidity contentions through a delayed application to this Court would strip the purpose of the requirement of said "ultra early

disclosure." Sanofi-Aventis, 598 F. Supp. 2d at 637. Therefore, this Court finds that Roxane's Motion is untimely as Roxane has not provided sufficient justification for its five month delay.

b. Good Cause

In addition to considering if the Motion is timely, the Court must also find that good cause exists. Rule 3.7 provides a non-exhaustive list, in its subsections, of circumstances that may constitute a showing of good cause. Roxane seeks to amend its Invalidity Contentions under subsection (b), which permits amendment where there has been "recent discovery of material prior art despite earlier diligent search." O2 Micro, 467 F.3d at 1366. Jazz argues that Roxane failed to conduct a diligent search, that the discovery was not recent, and that the documents do not constitute material prior art.

In order to illustrate good cause, there must be a showing of diligence. Id. The "burden is on the movant to establish diligence rather than on the opposing party to establish a lack of diligence." Id. Specifically, a good cause showing "requires diligence throughout the discovery process and that the moving party not only must act promptly upon discovery of new [information], but also must establish that it was diligent in its search." West v. Jewelry Innovations, Inc., Civil No. 07-1812, 2008 WL 4532558, at *2 (N.D. Cal., Oct. 8, 2008). Thus, in addition to considering if the application to the Court subsequent to discovery was timely, the court must consider if the movant "was diligent in discovering the basis for the proposed amendment." West, 2008 WL 4532558, at *2.

Here, Roxane argues that its discovery of the Alleged Prior Art was a result of a diligent search. Specifically, Roxane states that the Documents that are the subject of this Motion were not originally included in its Invalidity Contentions because they were not part of the prosecution

file history. (Def. Reply at 3-4). Further, during oral argument, Roxane stated that it did not have an obligation to search the FDA website for prior art. (Transcript at 80:10-19).

Roxane has failed to illustrate that it conducted a diligent search. The Alleged Prior Art that is the subject of this Motion is referenced on the face of the patents-in-suit. (Transcript at 19:16 – 23:16). In particular, the documents relate to an FDA presentation which was held on June 6, 2001. Roxane has failed to explain why these items were not originally discovered and included in its Invalidity Contentions. Roxane does not dispute that it had access to the prosecution file history of the patents-in-suit and knew of its contents. Instead, Roxane relies on the fact that all the Documents the Motion seeks to add were not submitted to the patent office. This Court finds Roxane's argument unpersuasive. Roxane has an obligation to conduct a diligent search of the patents-in-suit and, in particular, the documents referred to in the file history. In order for Roxane to prove that its discovery was recent, it must show what new information led to the discovery of the Alleged Prior Art. That is to say, Roxane must show its discovery was, in fact, recent. Here, Roxane has not satisfied this burden. The Documents that are the subject of this Motion were known - or should have been known - to Roxane because they were referenced on the face of the patent-in-suit.

Further, notwithstanding Roxane's contentions otherwise, Roxane had an obligation to conduct a public search for all relevant prior art in a diligent manner. Roxane states that it did not review the FDA website until it was making a final review of its contentions. Specifically, Roxane states that it discovered the Documents that are the subject of this Motion when it was time to dot its "I's" and cross its "T's". (Transcript at 9:20-10:7). A thorough review, however, should have been conducted when Roxane's Initial Invalidity Contentions were first due.

Roxane has not provided the Court with a reason as to why it did not originally review the FDA website, despite the references on the face of the patents-in-suit, other than to state it did not believe it had that obligation. Moreover, Roxane does not indicate what subsequent event triggered its desire to look to the FDA website in September of 2011. Instead, Roxane relies on Jazz's alleged lack of disclosure as a basis for not including the Documents in its Initial Invalidity Contentions. Jazz disputes this allegation. This Court finds Roxane's argument to be a distinction without a difference. The onus is not on Jazz to produce but, rather, Roxane to conduct a diligent search for prior art. This includes, but is not limited to, taking reasonable measures to review documents relating to the patents-in-suit and tailoring its public search appropriately. In this instance, Roxane should have conducted said search in September of 2011 when its Invalidity Contentions were originally due. As such, Roxane has failed to carry its burden in illustrating it has conducted a diligent search.

Next, Roxane argues that the Documents that are subject of the Motion are material prior art within the meaning of 35 U.S.C. § 102(b); in other words, that the Documents were sufficiently accessible to the public interested in the art. See In re Cronyn, 890 F.2d 1158, 1160 (Fed. Cir. 1989). Jazz contends, however, that the Documents fail to satisfy the requirements established by the Federal Circuit Court in order to be deemed prior art because they are not printed publication.

The Alleged Prior Art Roxane now seeks to add are the Preliminary Safety Review, the Video submitted to the FDA and a Transcript of that Video, the Briefing Booklet, the NADDI Presentation, the PCNSDAC Transcript and three Screen Shots. As to the Preliminary Safety Review, Roxane has not furnished the Court with sufficient information to conclude whether the Documents constitute prior art within the meaning of § 102(b).

Additionally, as to all videos, transcripts, briefing booklets, and presentations, Roxane has provided the Court with sufficient support to show that the information was physically available to the public. Roxane, however, has not shown that the Documents are "accessible to the interested public." See In re Cronyn, 890 F.2d at 1160. The Federal Circuit stated "a document is publically accessible if it has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, *exercising reasonable diligence, can locate it*...." Cordis Corp. v. Boston Scientific Corp., 561 F.3d 1319, 1333 (Fed. Cir. 2009) (emphasis added). Naturally, in order for the document to be publicly available, the source where the document was located must be one where, a person interested in the art, exercising reasonable diligence, would look for it.

Here, Roxane argued that it did not have an obligation to review the FDA website– the source of the Alleged Prior Art – when it originally submitted its invalidity contentions. If Roxane, a party actively engaged in litigation over the Distribution Patents, did not find the need to visit the FDA website to search for prior art during discovery, then why would others interested in the art look to the FDA website? That being said, this Court does not have sufficient information to conclude whether the public availability of these items is the type contemplated by § 102(b).

Finally, as to the Screen Shots, this Court finds that these items are not prior art pursuant to § 102(b). Roxane indicated the expense and effort it went to in order to obtain these Screen Shots, using complicated software to capture prior information on the FDA website. (Transcript at 11:22-12:19). That process indicates that the interested public could not obtain the information if they desired to review it. See Cordis, 561 F.3d at 1333. Therefore, Roxane has not carried its burden of establishing whether the Documents it seeks to add are material prior art

for the purposes of § 102(b). Without such a showing, this Court cannot permit an amendment of Roxane's Invalidity Contentions.

c. Undue Prejudice to Non-Movant

As to the undue prejudice prong, the Federal Circuit has made it clear that the Court only needs to consider undue prejudice if the moving party's application was timely and satisfies the good cause requirement. O2 Micro, 467 F.3d at 1368. Courts in this district, however, have addressed this prong where the movant has proffered a reason, albeit unpersuasive, for the untimeliness of the application and/or failure to illustrate good cause. See King, 2010 WL 2015258, at *4. This Court must consider whether permitting the proposed amendments would significantly delay the resolution of the dispute. Id. at 5. In particular, the Court must look to the present stage of the litigation and the impact of permitting an amendment on the non-moving party's trial strategy. Id. Here, relevant dates to consider include the due date for filing of Invalditiy Contentions, the due date of opening and responsive Markman briefs, and the date of the application.

Granting Roxane's Motion will likely unduly prejudice Jazz. When this application was made, the parties had already completed claim construction briefing and the Markman hearing was scheduled shortly thereafter. As previously noted, while Roxane reviewed and considered whether amending its Invalidity Contentions was appropriate, Jazz was operating under the previously filed contentions. For roughly ten (10) months, Jazz crafted its discovery based on the Invalidity Contentions filed with the Court. To permit an amendment would likely cause undue prejudice to Jazz by requiring additional discovery. The additional discovery would not only delay the disposition of this matter but also cause Jazz to reevaluate the strategy it has been

developing over the past year. Therefore, the delay would likely be unduly prejudicial to Jazz and further merits a denial of the Motion.

IV. Conclusion

For the reasons set forth above, the undersigned hereby **DENIES** Defendant's Motion. An appropriate order shall follow.

s/Cathy L. Waldor
CATHY L. WALDOR
UNITED STATES MAGISTRATE JUDGE